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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/469,606	12/22/1999	HEINZ PETER VOLLMERS	PATWA-2	5150
21559	7590	06/03/2005	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			HARRIS, ALANA M	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/469,606

Applicant(s)

VOLLMERS ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 42, 43 and 45-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 42, 43 and 45-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments and Arguments

1. Claims 1, 4, 42, 43 and 45-56 are pending.

Claims 51-56 have been added.

Claim 50 has been amended.

Claims 1, 4, 42, 43 and 45-56 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

3. The rejection of claim 50 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter) is withdrawn in light of Applicants' amendment to the said claim.
4. The rejection of claim 50 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicants' amendment to the claim.

Maintained Grounds of Rejection

Claim Rejections - 35 USC § 112

5. The rejection of claims 1, 4, 42, 43, 45-50 and newly added claims 51-56 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained and made. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants assert criteria that must be met to fulfill the written description requirement of 35 USC § 112, see pages 8, 9 12 and 13 of the Remarks submitted March 18, 2005. Applicants assert that their specification describes a publicly deposited cell line expressing the claimed glycoprotein, see first full sentence of page 10 of the submitted Remarks. Applicants conclude arguments that the claims do not recite variants and "...the combination of structural characteristics recited in the claims are sufficient to show that Applicants were in possession of the claimed glycoprotein at the time the application was filed.", see page 11 and page 13. These points of view and arguments have been carefully considered, but found unpersuasive.

The Examiner has plainly established during the entire course of prosecution reasons supported by the written description requirement explaining why Applicants claimed glycoprotein does not meet the said requirement. First and foremost Applicants must show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that Applicants were in possession of

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the claimed invention, see column 2, fifth paragraph of 1242 Official Gazette 172, January 30, 2001. The crux of the rejection is Applicants' inability to define the tumor-specific N-linked glycostructure and how one of ordinary skill in the art could identify the said structure. The claims do not define or characterize the glycostructure. Not knowing or not being able to clearly define the tumor specific N-linked glycostructure, which is germane to the claimed invention, implies that Applicants have not adequately described the species and consequently are not in possession of the genus. In view of Applicants not being able to define, nor characterize the glycostructure one of ordinary skill in the art is not clear on the variability that possibly exists within the genus of glycoproteins. And while Applicants state "[t]hese claims do not recite variants with deletions, insertions and/or substitutions in the amino acid primary structure of CD55 or in the amino acid primary structure of a section of this protein" (see page 11 of the Remarks) Applicants are reminded that claims are given the broadest interpretation, not within a vacuum and with reasonable consideration. The Examiner has meticulously provided Applicants with their own passages defining the claimed invention by page and line number detailing Applicants' language revealing the claimed invention, see Applicants' specification, page 5, lines 7-23 with particularity lines 18-23. Applicants' claims continue to read on a genus. There is a plethora of species that could be encompassed by the broad claims. Applicants are not entitled to all proteins capable of exhibiting this structure or containing the amino acid primary structure of CD55. For the reasons of record and the established analysis provided herein and of record there is insufficient to support the generic claims as provided by the Interim Written Description

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Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645 and the rejection is maintained.

Claim Rejections - 35 USC § 102

6. The rejection of claims 1, 43, 45-50 and newly added claims 51-56 under 35 U.S.C. 102(b) as being anticipated by Karnauchow et al. (Journal of Virology 70(8): 5143-5152, August 1996) is maintained.

Applicants argue Karnauchow does not teach an antigen recognized by Mab EVR1 as a glycoprotein having the amino acid primary structure of CD55 or a section of this protein and a tumor-specific N-linked glycostructure as set forth in the claims, see Remarks, page 14, last full sentence. In conclusion, Applicants assert that Karnauchow does not teach a glycoprotein having all the features of the claimed glycoprotein and the antibody noted in the claims, see page 16 of the Remarks. These points of view and arguments have been carefully considered but found unpersuasive.

Applicants have not provided sufficient scientific evidence establishing patentable differences between what is claimed and the prior art of Karnauchow. The glycoprotein of Karnauchow is found on a tumor cell, HeLa cell, which is not a normal cell and the glycoprotein is within the range of "about 82 kD" as set forth in claims 1 and 50. Applicants note that the CD55 on the HeLa cells recognized by Mab EVR12 is recombinantly expressed wild type human DAF (CD55), see page 15, first full paragraph of Remarks. This recombinant expression does not preclude this glycoprotein as not being a variant and in light of Applicants' definition of the claimed

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glycoprotein the prior art continues to read on the claims. As noted in the First Action on the Merits/ Request for Continued Examination mailed November 18, 2004 the disclosed protein and antibody appear to be the same as Applicants thereby inherently possessing a tumor-specific N-linked glycostructure and present on the specified cell line. The disclosed antibody is specific for the glycostructure and consequently is capable of presenting the results listed in claims 43, 45-49 and 51-56. Since the Patent and Trademark Office does not have the facilities for examining and comparing the glycoprotein and the antibody of the Applicants' with the protein and antibody of the prior art, the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the glycoprotein and antibody in the claimed invention to be used in the prior art. See *In re Best*, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.). Accordingly, the rejection is maintained.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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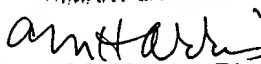
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 5:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER


Alana M. Harris, Ph.D.
29 May 2005